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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STOCKTON, LAURA LYNNE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,554	Applicant(s) CHAKRAVARTY ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 13-16 and 19-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-12, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :March 3, 2006 and August 18, 2008.

DETAILED ACTION

Claims 1-31 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-3, 8-12, 17 and 18 - drawn to products of Formula (I) wherein HET is a thiazole ring) in the reply filed on August 18, 2008 is acknowledged. The traversal is on the ground(s) that: (1) there is a single inventive concept in that the compounds are sodium channel blockers and thus, a search of the compounds in relation to their use would require no additional burden on the part of the Examiner to conduct the prior art search for examination of the present application in total; (2) there is minimal burden on the Examiner to examine Groups I-VI; and (3) rejoinder of the withdrawn method claims.

This is not found persuasive because the claims lack unity of invention since the special technical

feature, a biphenyl attached to a 5-membered nitrogen containing ring, does not define a contribution over the prior art. Further, it is strongly disagreed that additional searches would not impose an undue burden on the Examiner. Each of the outlined groups in the Lack of Unity requires separate search considerations. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources if the instant application were unrestricted. Additionally, since the elected products of Group I are not allowable, see below rejections, rejoinder at this time is not appropriate.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by Group I and Claims 4-7, 13-16 and 19-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 18, 2008.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on March 3, 2006 and August 18, 2008.

Oath/Declaration

The Declaration fails to comply with 37 CFR 1.497(a)(2) since PCT/US04/11271 is not identified in the Declaration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No written description can be found for the various second therapeutic agents listed in instant claim 18. For instance, the instant specification fails to disclose, discuss, define or describe what is meant by "opiate agonists", "opiate antagonists", etc. Therefore, claim 18 lacks written description as such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8-12, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, under the definition of HET, an "or" should be added before the last substituent listed.

In claim 1, under the definition of $R^1(f)$, there is a valence problem in the substituent "-C=C-" (page 49, line 15).

In claim 1, under the definition of $R^1(o)$, an "or" should be added (page 50, line 6) before definition (p).

In claim 1, under the definition of $R^a(d)$, there is a valence problem in the substituent "-C=C-" (page 50, line 33).

In claim 1, under the definition of $R^2(d)$, there is a valence problem in the substituent "-C=C-" (page 51,

line 25) and an "or" (page 51, line 25) is needed after definition (d).

In claim 1, under the definition of $R^3(d)$, there is a valence problem in the substituent "-C=C-" (page 52, line 8) and an "or" (page 52, line 9) is needed after definition (e).

In claim 1, under the definition of R^4 and $R^5(c)$, there is a valence problem in the substituent "-C=C-" (page 52, line 25).

In claim 1, under the definition of R^6 , R^7 and R^8 , an "or" (page 53, line 15) is needed after definition (d).

In claim 1, under the definition of R^6 , R^7 and $R^8(e)$, there is a valence problem in the substituent "-C=C-" (page 53, lines 22 and 33; and page 54, line 9).

Claim 1 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other

periods may be used elsewhere in the claims (page 53, line 36) except for abbreviations {i.e., "quinoxaliny1. benzofury1"}.

Claims 9-12 do not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

In claims 9-12, an "or" is needed before the last compound listed in each of the claims.

In claim 10, compounds where R⁶ represent "Cl" lack antecedent basis from claim 1.

Claim 18 is indefinite because the various types of second therapeutic agents are unclear and are not defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the

rejections under this section made in this Office
action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 17 and 18 are rejected under 35
U.S.C. 102(b) as being anticipated by:

- a) Oballa et al. {WO 2001/49288} - see, for example, the compound on page 17, lines 29-30;
- b) Brooks et al. {CA 134:207811, 2001} - see, for example, the compound of CA Registry No. 328919-78-4;
- c) Pick et al. {U.S. Pat. 5,462,959} - see the compound in column 5, lines 9-10;
- d) Tanaka et al. {U.S. Pat. 5,053,548} - see, for instance, Example 133 in Table 2 in columns 69-70; or
- e) Kimura et al. {CA 109:12776, 1988} - see the compound of CA Registry No. 114882-62-1.

Each of the above cited prior art disclose
compounds embraced by the instant claimed invention.

Therefore, each of the above cited prior art anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-12, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oballa et al. {WO 2001/49288}, Pick et al. {U.S. Pat. 5,462,959} and Tanaka et al. {U.S. Pat. 5,053,548}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims thiazole compounds. **Oballa et al.** (see entire document; particularly pages 2-5, 36 and

37; and especially the compound on page 17, lines 29-30), **Pick et al.** (see entire document; particularly columns 1-3; and especially the compound in column 5, lines 9-10) and **Tanaka et al.** (see entire document; particularly columns 1, 2, 37, 38; and especially Example 133 in Table 2 in columns 69-70) each teach thiazole compounds that are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814

(C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, asthma. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton, Ph.D.
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Work Group 1620
Technology Center 1600

September 4, 2008